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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,590	09/09/1999	ELIZABETH MOYER	00211-US-NEW	2967

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/393,590

Applicant(s)
Moyer et al.

Examiner
S. Devi, Ph.D.

Art Unit
1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 25, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 ~~is~~/are pending in the application.
- 4a) Of the above, claim(s) 29-53 ~~is~~/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 8, 14-17, 21, and 27 ~~is~~/are rejected.
- 7) ☒ Claim(s) 4, 6, 7, 9-13, 18-20, 22-26, and 28 ~~is~~/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

DETAILED ACTION

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 02/25/02 (paper no. 14) in response to the Office Action mailed 08/02/01 (paper no. 12).

Status of Claims

- 2) Claims 1-58 are pending in the instant application.
Claims 1 and 16 have been amended via the amendment filed 02/25/02.
Claims 1-28 are under examination.

Prior Citation of Title 35 Sections

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 6) The objection to the specification made in paragraph 6 of the Office Action mailed 10/24/00 is withdrawn in light of Applicants' amendment to the specification.

Rejection(s) Withdrawn

- 7) The rejection of claims 1-28 made in paragraph 9 of the Office Action mailed 10/24/00 (paper no. 8) and made and/or maintained in paragraph 9 of the Office Action mailed 08/02/01 (paper no. 12) under 35 U.S.C § 112, first paragraph, with regard to the scope, is withdrawn in light of Applicants' amendment to the base claims.

New Rejection(s)

- 8) Applicants are asked to note the following new rejection(s) made in this Office. The new rejection is necessitated, in part, by Applicants' amendments to the base claim(s).

Rejection(s) under 35 U.S.C § 102

- 9) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form

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the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10) Claims 1-3, 5, 8, 14-17, 21 and 27 are rejected under 35 U.S.C § 102(b) as being anticipated by Schantz *et al.* (*J. AOAC* 61: 96-99, 1978 - Applicants' IDS).

Schantz *et al.* teach a solvent composition comprising purified botulinum type A toxin in acetate buffer having a pH of 4.2 (i.e., about 5) for at least two years at room temperature. The preferable temperature is 18-24 degrees centigrade (see pages 96 and 97). The composition further includes gelatin and serum albumin (i.e., excipient protein) (see abstract and page 96). That Schantz's room temperature falls between the claimed range of 10-30 degrees centigrade or even between 0-10 degrees centigrade based on location, is inherent from the teaching of the prior art.

Claims 1-3, 5, 8, 14-17, 21 and 27 are anticipated by Schantz *et al.*

Prior Art

11) The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

● Schwarz (*Archiv. fur Lebensmittelhygiene* 30: 1-40, pp. 29-33, 1979 - original and translated documents) taught a stable liquid pharmaceutical formulation comprising an acetate buffer solution having a pH in the range of 4.5 to 5.6, or a phosphate buffer at a pH of 6.0 and a purified serotype B botulinum toxin. The toxin was purified and was stable at 15°C for 28 days. At the pH range of 4.5 to 6.0, a greater stability can be established at a storage temperature of 15°C than at the higher pH values (see abstract; Figures 1-3, 6, 7 and 9; and page 10, last paragraph). The toxin appears to be particularly stable at a pH value of 4.5. For a longer period, a solvent with a pH value under 6.0 appears to be more suitable (see page 12).

The page number indicated below refer to the page number of the translated document.

Remarks

12) Claims 1-3, 5, 8, 14-17, 21 and 27 stand rejected. Claims 4, 6, 7, 9-13, 18-20, 22-26 and 28 are objected to for being dependent on a rejected claim.

13) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile

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transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

14) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June, 2002


S. DEVI, PH.D.
PRIMARY EXAMINER